K102364

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Nydiag 200 Rotary Chair

DEC 23 2010

SUBMITTER INFORMATION

Company Name	Interacoustics A/S
Company Address	Drejervaenget 8 Assens, DK-5610, Denmark
Company Phone	+45 6371 3555
Company Fax	+45 6371 3522
Company e-mail	info@interacoustics.com
Contact Person	Erik Nielsen, Quality Manager
Date Summary Prepared	05. July 2010

DEVICE IDENTIFICATION

Trade Name	Nydiag 200
Common Name	Rotary Chair
Classification Name	Apparatus, vestibular analysis
Product Code	LXV
Panel	Ear Nose & Throat
Device Class	Unclassified

SUBSTANTIAL EQUIVALENCE

Predictive Device	System 2000 ROTATIONAL VESTIBULAR CHAIR
Manufacturer	Micromedical Technologies, Inc
510(k) No.	K922037
Date Cleared	10/26/1992

Device Description

The Nydiag 200 is a rotation chair, including a chair unit and a motor pedestal unit. The Nydiag 200 is controlled by software.

The rotating chair is an optional accessory and is used for stimulation of the patients balance organs. The chair is supplied from the mains and controlled from a computer through an USB connection.

Indications For Use

The Nydiag 200 rotary chair is an optional accessory for the Interacoustics eye movement recording systems. The rotary chair is used to elicit Vestibulo-Ocular Reflexes in patients aged 2 years or older who weigh less than 135 kg / 300 lbs who are being tested for bilateral or unilateral lesions in the peripheral vestibular organs.

Technological Characteristics
The chair unit includes the chair itself attached to a frame assembly, seat belts and other restraints, patient discomfort signal device and goggle connections (Firewire and USB). The pedestal includes a power unit and motor and gearing units.

Summary (Bech testing)
During bench test the device was tested according to appropriate standards and found safe and efficient according to the purpose of the device.

Conclusion
The Nydiag 200 was found to be equivalent to the predicate device in technological characteristics and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Interacoustics A/S
c/o Mr. Erik Nielsen
Quality Manager
Drejervaenget 8
Assens, DK-5610
Denmark

DEC 23 2010

Re: K102364
Trade/Device Name: Nydiag 200 Rotary Chair
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LXV
Dated: November 9, 2010
Received: November 12, 2010

Dear Mr. Nielsen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Applicant: Interacoustics A/S

DEC 2 3 2010

510(k) Number (if known): **K102364**

Device Name: Nydiag 200

Indications For Use:
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Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K102364

Prescription Use
(Per 21 CFR 801.109)

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